Guerbet

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June 9, 2010

Dear Healthcare Professional,

Due to the current critical shortage of **ETHIODOL®, Brand of Ethiodized Oil Injection**, Guerbet is coordinating with the FDA to increase the availability of the ethyl esters of iodized fatty acids of poppy seed oil product.

Guerbet has acquired the Ethiodol® NDA from Nycomed US Inc. effective May 7, 2010 and is working with the FDA to resume manufacturing of Ethiodol in the near future to ensure continued availability for the US patients. During this interim period, Guerbet, in conjunction with the FDA, is initiating a temporary importation of **LIPIODOL® ULTRA-FLUIDE**, ethyl esters of iodized fatty acids of poppy seed oil, to the United States market. **LIPIODOL® ULTRA-FLUIDE** contains the same drug components as **ETHIODOL®, Brand of Ethiodized Oil Injection,** (previously manufactured and marketed in the United States by Savage Laboratories, a subsidiary of Nycomed). **LIPIODOL® ULTRA-FLUIDE** is manufactured in compliance with European Good Manufacturing Practice (GMP) regulations by Delpharm Tours (France) for Guerbet.

At this time, no other entity except Guerbet is authorized by the FDA to import or distribute **LIPIODOL® ULTRA-FLUIDE**. Any sales of **LIPIODOL® ULTRA-FLUIDE** ampoules from any entity other than Guerbet will be considered in violation of the Federal Food, Drug and Cosmetic Act and may be subject to enforcement action by the FDA.

Effective immediately, Guerbet will offer the following version:

LIPIODOL® ULTRA-FLUIDE **48% Iodine w/vol (i.e 480 mg Iodine/mL)** (ethyl esters of iodized fatty acids of poppy seed oil)	
10mL glass ampoule	Authorization# 306 216.0 Box of 1 ampoule

LIPIODOL® ULTRA-FLUIDE formulation is similar to ETHIODOL®.

The active substance of LIPIODOL® ULTRA-FLUIDE and ETHIODOL is the same (ethyl esters of iodized fatty acids of poppy seed oil, stabilized with 1% of poppy seed oil). It is important to note that there are some key labeling differences between the international marketed **LIPIODOL® ULTRA-FLUIDE** and the United States marketed **ETHIODOL®** that you need to be aware:

- **The difference in label claim is due to the unit used to express the Iodine content: the unit for ETHIODOL® is 37% Iodine w/w = weight/weight, while the unit for LIPIODOL ULTRA-FLUIDE® is 48% Iodine w/vol= weight/volume. When converting one unit to another (w/w or w/vol), the Iodine content of ETHIODOL® and LIPIODOL® ULTRA-FLUIDE are similar.**

The barcode used on **LIPIODOL® ULTRA-FLUIDE** is an international pharmaceutical manufacturing code and will likely not be recognized by scanning systems used in the United States. Institutions should confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures

should be followed to assure that the correct drug product is being used and administered to individual patients.

For questions regarding **LIPIODOL® ULTRA-FLUIDE** in the United States, please contact Guerbet LLC at 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (EST), or email at info-us@guerbet-group.com.

The product comparison table below also highlights the differences between **LIPIODOL® ULTRA-FLUIDE** and **ETHIODOL®**.

Please click here for package inserts: Guerbet **LIPIODOL® ULTRA-FLUIDE** and Savage Laboratories **ETHIODOL®**

- **Customers can order directly from Guerbet LLC by contacting Customer Service at 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (EST).**
- **LIPIODOL® ULTRA-FLUIDE is not refundable and not for resale.**

Guerbet will make reasonable attempts to fill your orders. Guerbet will be closely monitoring the distribution of **LIPIODOL® ULTRA-FLUIDE** to help manage the supply.

If you have additional questions, please contact Customer Service at 1-877-729-6679, Monday through Friday, between the hours of 8 a.m. and 5 p.m. (EST), or email customer.service-us@guerbet-group.com. This communication and updated product information is available on the Guerbet website at http://www.guerbet-us.com as well as on the FDA Drug Shortage website at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm.

To report adverse events among patients administered, please call 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (EST), or email medical.liaison@guerbet-group.com.

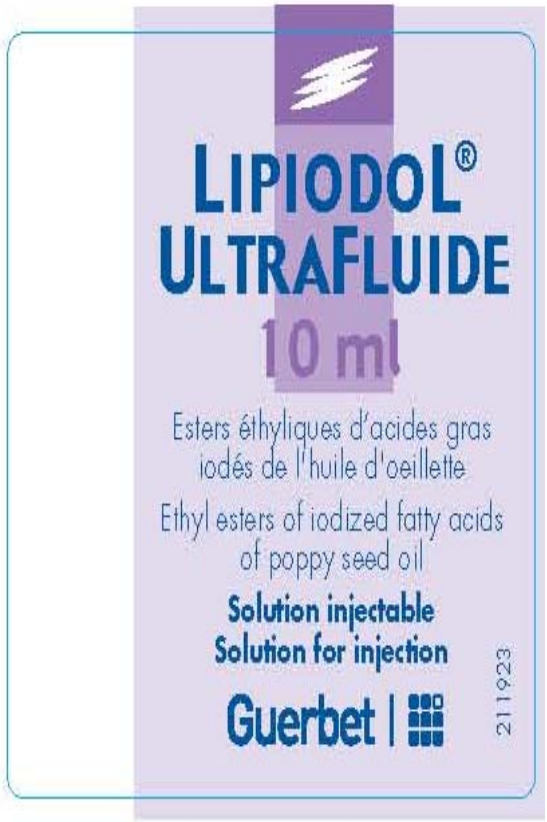
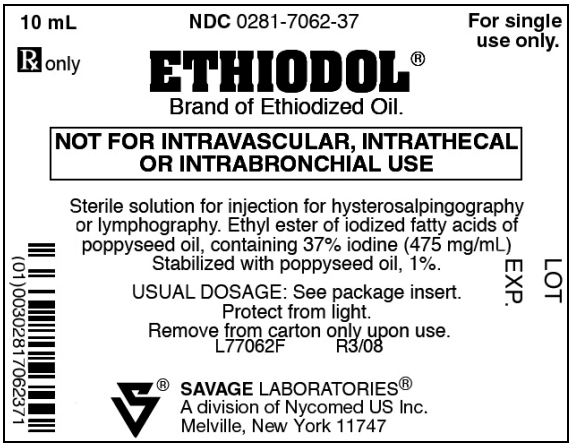
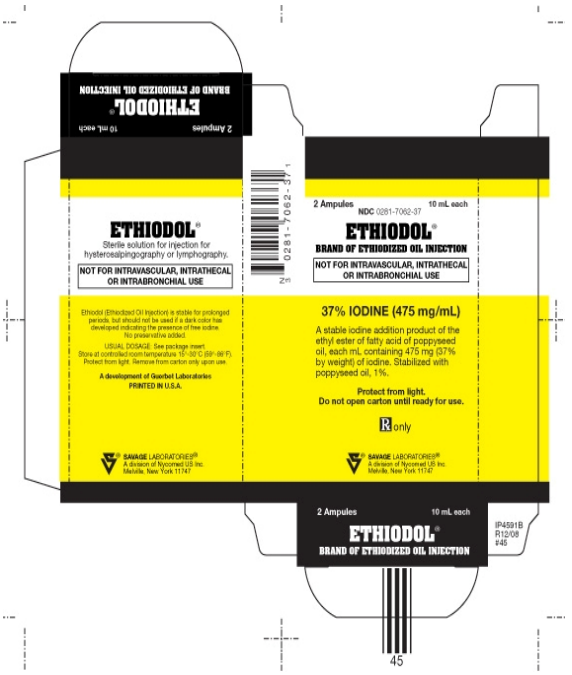
Alternatively, any adverse events that may be related to the use of these products should be reported to the FDA's Med Watch Program by fax at 1-800-FDA-0178, by mail at Med Watch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the Med Watch website at http:www.fda.gov/safety/medwatch/default.htm.

We urge you to contact our Medical Information Department at 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (EST), or email medical.liaison@guerbet-group.com if you have any questions about the information contained in this letter or the safe and effective use of **LIPIODOL® ULTRA-FLUIDE.**

Sincerely,

Corina Harper
Compliance Manager, Guerbet LLC

Comparison Table

LIPIODOL® ULTRA-FLUIDE ampoule label	ETHIODOL® ampoule label
	
LIPIODOL® ULTRA-FLUIDE carton label	**ETHIODOL® carton label**
	

LIPIODOL® ULTRA-FLUIDE (ethyl esters of iodized fatty acids of poppy seed oil)	**ETHIODOL®** (ethyl esters of iodized fatty acids of poppy seed oil)
Iodine label claim	
48% w/vol Iodine (480 mg/mL)	**37% w/w Iodine (475 mg/mL)**
Indications and contraindications	
See package insert **Please note: see package insert sections 4.2 Method of administration, 4.3 Contraindications, and 4.4 Special warning and precautions for use.**	**ETHIODOL®** is indicated for use as a radio-opaque medium for hysterosalpingography and lymphography. See package insert for contraindications.
Barcode	
Barcode use by **LIPIODOL® ULTRA-FLUIDE** may not register accurately in the United States scanning systems. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.	A unit of use barcode is on individual ampoules.
How supplied	
Box of 1 ampoule Authorization# 306 216.0	Box of 2 ampoules NDC# 0281-7062-37
Additional information	
Contains a patient information leaflet	N/A